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placing the cushion on the anterior portion of the chest of the patient;

securing the band around the chest of the patient and over the cushion; and

inflating the fluid-receiving cells to compress the chest of the patient.

Remarks

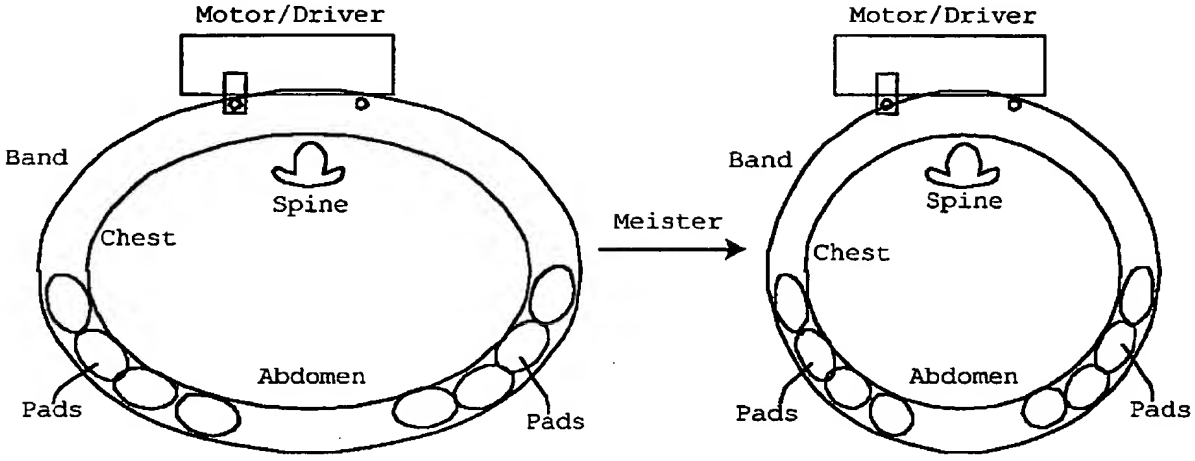
Claims 1 through 13 remain pending in the application. Claims 14 through 21 are added by this amendment.

Applicant amended claim 1 to delete the word "circumferentially." Applicant also amended the claims to correct grammatical errors. Applicant has added claims 14 through 18 to further specify the relationship of the cushion with respect to the band and the patient. Applicant has also added method claims 19 through 21 based on the device claims. None of the claims are shown or suggested by the cited references.

The Office Action rejected claim 1 as obvious over Meister, Artificial Respirator, U.S. Patent 2,486,667 (Nov. 1, 1949), in view of Bastyr et al., Orthopedic Brace Having A Pneumatic Pad And Associated Pump, U.S. Patent 5,520,622 (May 28, 1996) under the assertion that Meister teaches a band, a driver mechanism, a cushion and an automatic controller inside the driver mechanism to control the timing of compression cycles, that Bastyr teaches fluid-filled cushion pads, and that it would have been obvious to modify Meister to use fluid filled cushions as taught by Bastyr to provide a soft pad having a hardness and size that is variable.

Meister teaches away from claim 1. Meister

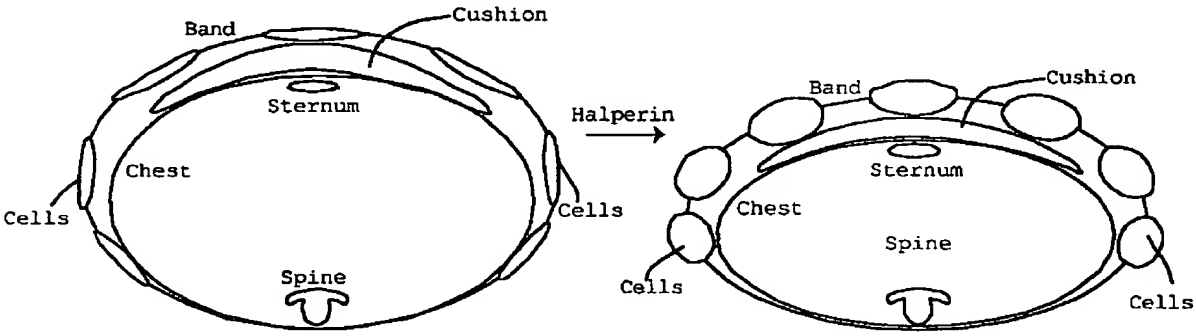
discloses pads located about the abdomen, and operates as illustrated below:



Meister suggests no other placement of the pads. If moved up around the patient's chest, Meister would compress the patient's ribs preferentially with respect to the sternum, thus squeezing the sides of the chest. Preferentially squeezing the sides of the chest produces little, if any, blood flow, while anterior-posterior compressions obtainable with the claimed device (compressing the chest over the sternum) results in significant blood flow. By directing force against the lateral portions of the rib cage (if modified for use above the abdomen), Meister would accomplish lateral compression of the ribcage, lifting the sternum, leaving the heart uncompressed. Thus, all the power expended on compression would be wasted in ineffectual deformation of the chest without significant hemodynamic effect. Thus, the proposed combination would result in a non-working device, and one skilled in the art would have been motivated to avoid the modifications suggested by the Examiner (if they understood the mechanical reaction of the chest to compressions, and it effects on blood flow (if not, they might have made an unmotivated modification which would have proved ineffective in producing blood flow)).

In addition, squeezing the sides of the chest would substantially increase the probability that the patient's ribs would break during compressions, possibly causing severe internal damage. Given the strong motivation to avoid this outcome, one skilled in the art would avoid Meister when designing a device or method for performing chest compressions. Thus, Meister teaches away from claim 1.

Applicant's claimed device, on the other hand, preferentially compresses the sternum, as shown in Figure 8 of the application, and futher illustrated below:



The figures illustrate that the proposed combination does not meet the limitations of claim 1. Neither Meister nor Bastyr shows a fluid-filled cushion disposed between the chest of the patient and the band. Meister places pads around the band and the pads directly contact the abdomen. Bastyr likewise uses pads that directly contact the abdomen. (Adding the pads from Bastyr to Meister is redundant since Meister already uses pads disposed around the band.) No one skilled in the art would combine Meister and Bastyr to obtain Applicant's claimed invention since those references simply do not show or suggest a cushion disposed between the band and the patient's chest. Thus, the proposed combination cannot meet the limitations of claim 1.

In addition, Meister provides a device for compressing the *abdomen* to provide artificial respiration and Bastyr shows a completely unrelated knee brace. Meister does not suggest that his device can be used as a chest compression device to increase blood flow in the patient and Bastyr certainly provides no such suggestion. Given the uncertain hemodynamic effects of moving Meister's device up around the chest, no one would consider Meister a chest compression device. Thus, neither Meister nor Bastyr suggest a fluid-filled cushion disposed between the chest of the patient and the band. Thus, again, the proposed combination does not meet the limitations of claim 1. Accordingly, claim 1 is non-obvious.

In addition, the Office Action has not suggested a motivation to combine the references. Instead, the Office Action states that, "it would have been obvious… to modify Meister… to provide a soft pad having a hardness and size that is variable." This statement is, at best, a possible result of combining Meister and Bastyr, but the statement provides no reason *why* one skilled in the art would be motivated to modify Meister. (The statement also provides no motivation for why one would move the band from the abdomen to the chest.) Indeed, the statement is meaningless absent a prior suggestion that the pad should have a variable hardness and size. In the case at hand, only applicant's disclosure provides for a fluid-filled cushion between the band and the patient's chest. Meister and Bastyr are devoid of any such disclosure or suggestion. Accordingly, the Office Action has failed to fashion a prima facie obviousness rejection.

Moreover, there is no motivation to combine or otherwise modify the references. Meister is over 50 years old. Fluid-filled pads such as those provided in Bastyr have existed at least that long. Given the stark reality of millions of deaths from cardiac arrest over those years, a strong motivation has existed to provide a device to save victims of cardiac arrest. Thus, if

the proposed modification of Meister were obvious, then the proposed device would have been on the market for many years. The failure of anyone to suggest, build or market the proposed device for over 50 years indicates that there is no motivation to combine or modify the references. That same failure also shows that Meister does not work as a chest compression device. Accordingly, claim 1 is non-obvious.

Further with respect to the non-existence of a motivation to modify Meister, Meister provides a device for compressing the abdomen to effect artificial respiration, not for compressing the chest. There is no indication that Meister is capable of chest compressions to the degree (that is, at an effective pace and depth of compression) necessary to effect blood flow. Thus, there is no motivation to modify Meister.

In addition, in a previous advisory action the Examiner suggested that the cushions are added for comfort. It is counterproductive to add cushions for comfort if doing so interferes with compressing the chest. The success of CPR depends on the hemodynamic effect created by the device used. That effect is impossible to predict in the Meister device. Thus, Meister provides no indication that adding cushions would work in a CPR device. No one would be motivated to reduce the chances of the patient's survival by creating a substandard chest compression device, so there is no motivation to modify Meister for use as a chest compression device. (Indeed, as described above, one skilled in the art would recognize that Meister is likely to injure the patient when deployed at the level of the chest.) Also, comfort is clearly not a motivation when dealing with unconscious patients, and all cardiac arrest patients are unconscious.

In addition, Bastyr is non-analogous art with respect to the claims. To be analogous, the reference must either be in the field of applicant's endeavor or be reasonably pertinent to the

particular problem with which the inventor was concerned. In re Oetiker, 977 F.2d 1443, 1446 (Fed. Cir. 1992). Bastyr shows an orthopedic knee brace having fluid-filled cushion pads to secure the brace around the knee and to increase patient comfort. In contrast, claim 1 is directed to a device for compressing the chest of a patient. The two devices are, on their face, in utterly unrelated fields. Similarly, Bastyr is not reasonably pertinent to the particular problem with which the inventor was concerned. Applicant certainly was not concerned with patient comfort or with supporting the patient's knee. There is utterly no reason for a person designing a chest compression device, to treat heart attack victims, to look at knee braces for a solution to any problem that might be encountered. Though both may be referred to as medical devices, it makes no sense to expect one of ordinary skill in the art of chest compression devices to look at knee braces. Thus, Bastyr is non-analogous art with respect to claim 1. Accordingly, claim 1 is non-obvious.

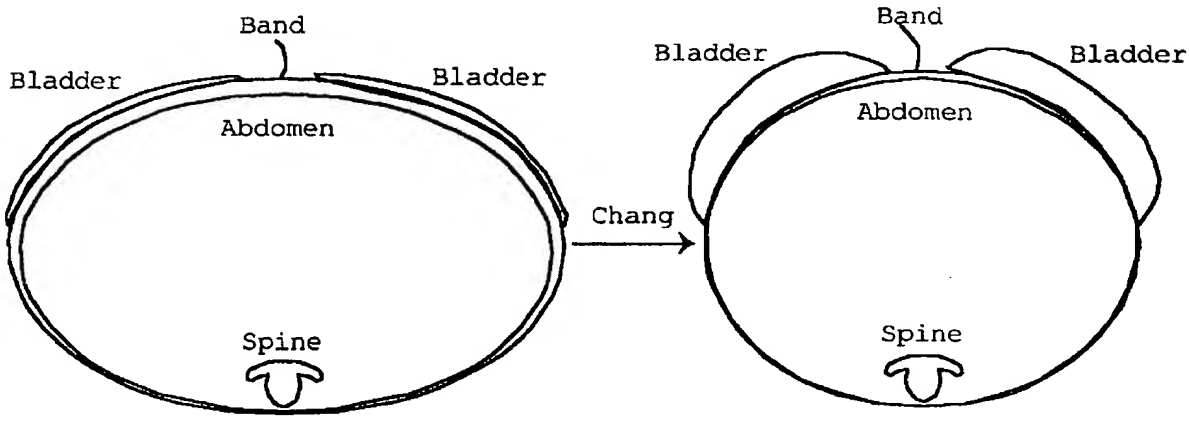
In the Advisory Action, the Examiner stated that, "the problem to be solved is providing cushion and comfort to the patient when applying structures that fit tightly around the patient and apply pressure to body parts." Apparently, this is the reason that Bastyr is still maintained as a reference. However, common sense dictates that the comfort of a heart attack victim is irrelevant. There is no such motivation for a CPR device, where the patient is dying of heart attack. The patient is unconscious and is utterly incapable of discerning whether the device is comfortable. In addition, current guidelines for CPR indicate that chest compressions should continue even if an operator hears ribs breaking (though a rescuer or device should avoid breaking ribs.) The comfort motivation does not apply in the art: Better to be alive with a painful broken rib than dead but comfortable. Accordingly, the purported problem to be solved is non-existent. Thus, Bastyr remains non-analogous art to the claims.

The Examiner has not addressed Applicant's prior explanation that patient comfort is not a motivation and is not related to the problem to be solved. Currently, the position of the emergency medical community is that patient comfort is irrelevant, even to the point of continuing compression after breaking ribs, and the hypothetical comfort motivation is clearly contrary to the weight of medical opinion. If the Examiner has a basis for the assertion that patient comfort is a motivating factor in the art of CPR, or otherwise relevant to problems in CPR, the Applicant requests disclosure of that basis so that it may be countered.

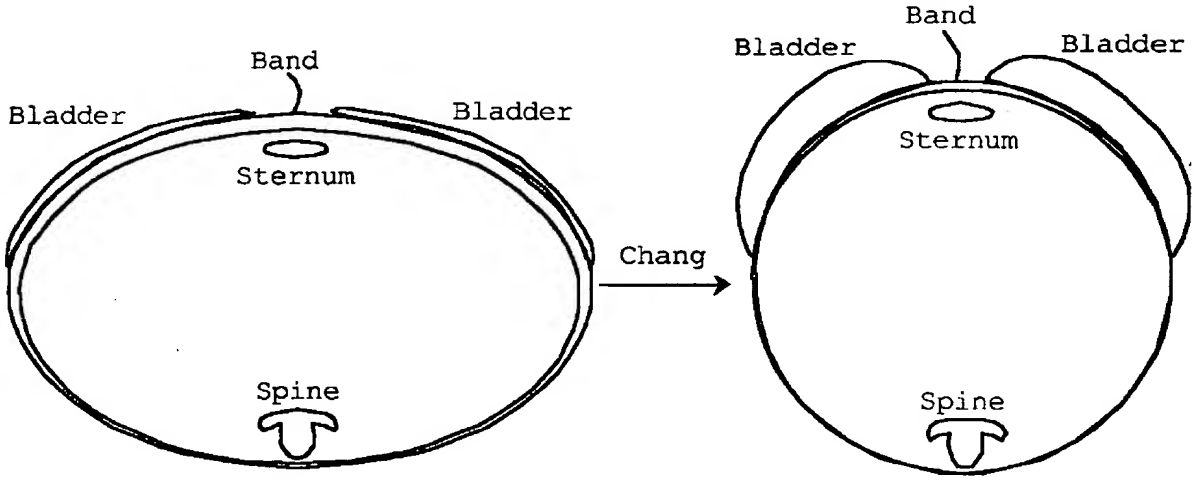
The Office Action rejected claims 2 through 13 as obvious over Chang, Method and Apparatus for Applying High Frequency Extrathoracic Induced Breathing, Canadian Patent 1,225,889 (Aug. 25, 1987), in view of Meister, under the assertion that Chang teaches a band including a plurality of fluid receiving cells and a reciprocating pump for automatically supplying fluid to the cells, that Meister teaches a device for compressing the chest and the need for providing compression pads between the band and the chest, and that it would have been obvious to modify Chang to provide compression pads disposed between the chest and the band as taught by Meister to enhance respiration producing action of the device. Regarding claims 3, 6, 9 and 12, the Office Action states that it would have been obvious to provide a sealed cushion so that moisture from the patient doesn't saturate the cushion. Regarding claims 5, 8 and 11, the Office Action states that the two fluid-receiving cells are in fluid communication with each other because the tubes shown in Chang are linked together.

The proposed combination does not meet the limitations of the claims. Both Chang and Meister show a belt disposed around the patient's abdomen. Thus, any combination of Chang and Meister cannot show a cushion disposed between the chest of the patient and the band. Since the proposed combination does not meet the limitations of the claims, the claims are non-obvious.

In addition, Chang teaches away from the claims. Chang compresses the patient's abdomen, as shown below:



If Chang's device were moved up and placed around the chest, and further modified so that it could compress the chest, Chang's device would squeeze the patient's sides preferentially with respect to the sternum, as shown in the figures below:



Preferentially squeezing the sides of the chest produces little if any blood flow, while anterior-posterior compressions obtainable with the claimed device (compressing the chest over the sternum) results in significant blood flow. By directing force against the lateral portions of the rib cage (if modified for use above the

abdomen), Chang would accomplish lateral compression of the ribcage, lifting the sternum, leaving the heart uncompressed. Thus, all the power expended on compression would be wasted in ineffectual deformation of the chest without significant hemodynamic effect. Squeezing the sides of the chest also increases the chances of breaking ribs, as does performing compressions with the relatively narrow band disclosed in Chang. One skilled in the art would recognize these problems and thus be strongly motivated to avoid using the Chang device for chest compressions. Thus, Chang teaches away from the claimed invention, and requires several claimed non-obvious modifications before it is suitable for use in CPR.

Moreover, Chang states that the pressure in the bladders should be from about 10 cm of water to about 120 cm of water. This pressure corresponds to about 0.1 PSI to about 1.7 PSI. Applicant, on the other hand, specifies that chest compressions use about 20 PSI in his bladders. The pressure range stated by Chang is roughly an order of magnitude less than the pressure needed to compress the patient's chest. Since Chang's device uses a pressure that is too low to effect chest compressions, one skilled in the art would be motivated to avoid using Chang's device. (Meister adds nothing to the proposed combination since Meister is also a device designed to enhance respiration by compressing the abdomen.) Thus, Chang teaches away from the claims.

Similarly, Meister teaches away from the claims. As described above, if one moved Meister's device up and around the patient's chest, the patient's ribs would be compressed preferentially with respect to the sternum. This would produce little, if any, blood flow. This would also substantially increase the probability that the patient's ribs would break during compressions, causing severe internal damage. Given the strong motivation to avoid these outcomes, one skilled in the art

would avoid Meister when designing a device or method for performing chest compressions. Thus, Meister teaches away from the claimed inventions.

In addition, the Office Action has not stated a motivation to combine the references. The Office Action has asserted purported advantages to combining the references with statements such as, "to enhance the respiration producing action of the device" and "to provide a sealed cushion so that moisture from the patient doesn't saturate the cushion." However, these statements do not state *why* one skilled in the art would have been motivated to combine or otherwise modify the references.

Furthermore, the purposed advantages suggested by the Office Action cannot be considered motivations to combine the references to achieve a CPR compression device. Regarding the statement that the addition of pads would enhance respiration, there is no foundation for this statement. There is no indication in the prior art to indicate that adding pads to a chest compression device somehow increases respiration in the patient during chest compressions. Respiration during CPR is provided by ventilation, using additional devices to inflate the patient's lungs, so it would be superfluous to attempt to improve respiration due to compression. In fact, it is clearly contraindicated. CPR compressions should be rapid (80 compressions per minute) while ventilation should be accomplished by ventilation between sets of compressions (when the compressions are not occurring) at a much slower rate. ACLS guidelines do not provide for rapid ventilation, and the Office Action is merely speculating that aerodynamic effect is enhanced by modifications that enhance hemodynamic effect, and that oxygen uptake in the lungs would benefit from rapid ventilation (as opposed to benefiting from the currently accepted ventilation rates). These speculative conclusions require a detailed understanding oxygen uptake in the longs, and how it is effected by breathing rates far exceeding

normal breathing rates, and some indication that these understandings exist in the art and would motivate a modification of the references. The Office Action provides no such support for the rejection based on the Examiner's assertion that enhancing respiration would be a motivation for combining the references, and the rejection should be withdrawn.

Regarding the stated advantage of sealing the cushions from moisture, this statement cannot be a motivation to combine the references. Saturation of an unsealed cushion might well improve a CPR device by limiting the compressibility of the cushion. Thus, preventing a wet cushion is not an existing motivation to do anything in regards to chest compression devices. In addition, Chang indicates a benefit to leaking fluid receivers, making it impossible to ascertain any benefit to adding sealed cushions to leaking fluid receiving cells, since the leaking cells would have uncertain interaction with the sealed cells. Thus, Chang explicitly discloses a motivation directly contrary to the hypothetical statement posited by the Examiner. Accordingly, the stated advantage cannot be considered a motivation to combine the references. Since the Office Action has not stated any motivation to combine or otherwise modify the references in this regard, the Office Action has failed to state a prima facie obviousness rejection, and the rejection should be withdrawn.

Moreover, there is no motivation to combine or otherwise modify Chang or Meister, as evidence by the long-felt need for Applicant's invention. Meister is over 50 years old. Chang has been published for over 15 years. Given the stark reality of millions of deaths from cardiac arrest over those years, a strong motivation has existed to provide a device to save victims of cardiac arrest. Thus, if the proposed modification of Chang were obvious, then the proposed device would have been on the market for years. The failure of anyone to suggest, build or market the proposed device for over 15 years indicates that there is no

motivation to combine or modify the references. Moreover, that failure also shows that neither Chang nor Meister work as a chest compression device. Accordingly, the claims are non-obvious.

In addition, Chang and Meister are complete and functional in and of themselves and therefore there is no reason to add elements from Meister to Chang. Meister functions by drawing a belt over the abdomen of the patient (cushions might well enhance patient comfort in this case). Chang operates with bladders, so there is no need for cushions to provide comfort. Since the references are complete in and of themselves, the claims are non-obvious.

Now addressing specific claims, for claims 8 and 11 neither Chang nor Meister shows or suggests a manifold or a linking portion linking the bladders or cells. Thus, the proposed combination does not meet the limitations of claims 8 and 11. Accordingly, claims 8 and 11 are non-obvious.

Regarding claims 14 through 18, neither Chang nor Meister shows a cushion sized and dimensioned to cover substantially the entire anterior portion of the chest. Chang shows a band that is about 4 inches wide along the superior-inferior direction of the patient. The average chest of the patient is about 9 inches along the superior-inferior direction. Thus, the Chang belt does not cover substantially the entire anterior portion of the chest of the patient. (The size difference is significant since the size of the band greatly affects the efficacy of chest compressions.) Meister does not discuss the size of his band, other than to say that it is "relatively wide." Given that his band is adapted to be placed around the patient's abdomen, his belt is about as large as Chang's. Thus, Meister also does not show a belt sized and dimensioned to cover substantially the entire anterior portion of the chest of the patient. Thus, the proposed combination cannot show or suggest the limitations of claims 14 through 18.

Regarding claims 19 through 21, neither Chang nor Meister shows a method of compressing the chest and neither shows or suggests the step of providing the claimed devices. Thus, claims 19 through 21 are non-obvious.

Conclusion

This response has addressed all of the Examiner's grounds for rejection. The rejections based on prior art have been traversed. Reconsideration of the rejections and allowance of the claims is requested.

Date: June 16, 2003 By: _____

K. David Crockett, Esq.
Reg. No. 34311

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of:	
Halperin	Art Unit: 3764
Serial No.: 09/954,544	
Filed: September 12, 2001	
For: Automated Chest Compression Apparatus	Examiner: DeMille, D.

ATTACHMENT OF CLAIMS AND AMENDED SPECIFICATION PARAGRAPHS

The claims, including those amended by the Response submitted herewith on June 16, 2003, are as follows:

1. (amended) A device for compressing the chest of a patient comprising:

a band adapted to extend around the chest of the patient;

a driver mechanism, operably connected to the band, for [circumferentially] contracting the band;

a fluid-filled cushion disposed between the chest of the patient and the band; and

an automatic controller for controlling operation of the driver mechanism.

2. (amended) A device for compressing the chest of a patient comprising:

a band adapted to extend around the chest of the patient, the band having [a length and] a plurality of fluid-receiving cells disposed along the length of the band;

a driver mechanism, operably connected to the band, for inflating the fluid-receiving cells;

a cushion disposed between the chest of the patient and the band; and

an automatic controller for controlling operation of the driver mechanism.

3. (unchanged) The device of claim 2, wherein the cushion is a sealed cushion.

4. (unchanged) The device of claim 2, wherein the band is comprised of an inelastic material.

5. (amended) A device for compressing the chest of a patient comprising:

a band adapted to extend around the chest of the patient, the band having [a length and] a plurality of fluid-receiving cells disposed along the length of the band, wherein the plurality of fluid-receiving cells are in fluid communication with each other;

a driver mechanism, connected to the band and the fluid-receiving cells, for inflating the fluid-receiving cells;

a cushion disposed between the chest of the patient and the band; and

an automatic controller for controlling the operation of the driver mechanism.

6. (unchanged) The device of claim 5, wherein the cushion is a sealed cushion.

7. (unchanged) The device of claim 5, wherein the band is comprised of an inelastic material.

8. (amended) A device for compressing the chest of a patient comprising:

a band adapted to extend around the chest of the patient, the band having [a length and] a plurality of fluid-receiving cells disposed along the length of the band, each fluid-receiving [cells] cell being interconnected to another fluid-receiving [cells] cell by a [linking portion] manifold;

a driver mechanism, operably connected to the band, for inflating the fluid-receiving cells;

a cushion disposed between the chest of the patient and the band; and

an automatic controller for controlling operation of the driver mechanism.

9. (unchanged) The device of claim 8, wherein the cushion is a sealed cushion.

10. (unchanged) The device of claim 8, wherein the band is comprised of an inelastic material.

11. (amended) A device for compressing the chest of a patient comprising:

a band adapted to extend around the chest of the patient, the band having [a length and] a plurality of fluid-receiving cells disposed along the length of the band, each fluid-receiving [cells] cell being interconnected to another

fluid-receiving [cells] cell by a [linking portion] manifold, wherein the plurality of fluid-receiving cells are in fluid communication with each other;

a driver mechanism, connected to the band and the fluid-receiving cells, for inflating the fluid-receiving cells;

a cushion disposed between the chest of the patient and the band; and

an automatic controller for controlling the operation of the driver mechanism.

12. (unchanged) The device of claim 11, wherein the cushion is a sealed cushion.

13. (unchanged) The device of claim 11, wherein the band is comprised of an inelastic material.

14. (new) The device of claim 1 wherein the cushion is sized and dimensioned to cover substantially the entire anterior portion of the chest of the patient.

15. (new) The device of claim 2 wherein the cushion is sized and dimensioned to cover substantially the entire anterior portion of the chest of the patient.

16. (new) The device of claim 5 wherein the cushion is sized and dimensioned to cover substantially the entire anterior portion of the chest of the patient.

17. (new) The device of claim 8 wherein the cushion is sized and dimensioned to cover substantially the entire anterior portion of the chest of the patient.

18. (new) The device of claim 11 wherein the cushion is sized and dimensioned to cover substantially the entire anterior portion of the chest of the patient.

19. (new) A method of compressing the chest of a patient, said method comprising the steps of:

providing a device for compressing the chest of a patient, said device comprising:

a band adapted to extend around the chest of the patient;

a driver mechanism, operably connected to the band, for contracting the band;

a fluid-filled cushion sized and dimensioned to cover substantially the entire anterior portion of the chest of the patient; and

an automatic controller for controlling operation of the driver mechanism;

placing the cushion on the anterior portion of the chest of the patient;

securing the band around the chest of the patient and over the cushion; and

contracting the band to compress the chest of the patient.

20. (new) A method of compressing the chest of a patient, said method comprising the steps of:

providing a device for compressing the chest of a patient, said device comprising:

a band adapted to extend around the chest of the patient, the band having a plurality of fluid-receiving cells disposed along the length of the band;

a driver mechanism, operably connected to the band, for inflating the fluid-receiving cells;

a cushion sized and dimensioned to cover substantially the entire anterior portion of the chest of the patient; and

an automatic controller for controlling operation of the driver mechanism;

placing the cushion on the anterior portion of the chest of the patient;

securing the band around the chest of the patient and over the cushion; and

inflating the fluid-receiving cells to compress the chest of the patient.

21. (new) A method of compressing the chest of a patient, said method comprising the steps of:

providing a device for compressing the chest of a patient, said device comprising:

a band adapted to extend around the chest of the patient, the band having a plurality of fluid-receiving cells disposed along the length of the band, wherein each of the fluid-receiving cells is in fluid communication with a manifold;

a driver mechanism, operably connected to the band, for inflating the fluid-receiving cells;

a cushion sized and dimensioned to cover substantially the entire anterior portion of the chest of the patient; and

an automatic controller for controlling operation of the driver mechanism.

placing the cushion on the anterior portion of the chest of the patient;

securing the band around the chest of the patient and over the cushion; and

inflating the fluid-receiving cells to compress the chest of the patient.

End